

FLIGHT CONTROL PLUS

FOR GEESE REPELLENCY

EPA Reg. No. 69969-1
EPA Est. No. 62171-MS-1

ACTIVE INGREDIENT

9, 10 anthraquinone 50%

INERT INGREDIENTS 50%

Total 100%

For Best Results: Product may separate if allowed to sit. Resuspend with agitation. Keep from freezing.

KEEP OUT OF REACH OF CHILDREN CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing vapor or spray mist. Remove contaminated clothing and wash clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment or disposal of waste. Apply this product only as specified on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

This product may be used to repel geese, including Canada geese.

For Professional Application to Lawns.

- Repels geese from terrestrial areas at or near airports.
- Repels geese from grassy areas at commercial sites, industrial sites, municipal sites or in developed urban areas.
- Repels geese from golf courses.
- Repels geese from landfills and dumpsites.

To prevent contamination of the dilute solution of Flight[®] Control Plus by other chemical residues, be sure that the equipment is thoroughly clean before use or use dedicated equipment.

This product must be applied using properly calibrated and maintained spray equipment. Do not apply when surface to be treated is wet or when rain is expected. For best results, product should dry on turf grass surface prior to rainfall. Mowing treated areas will remove product and reduce product effectiveness.

For sale to and application by professional applicators only. Do not apply this product in a way that will contact workers or other persons, either directly or through drift.

MIXING DIRECTIONS:

Thoroughly shake or stir Flight Control[®] Plus prior to diluting with water.

APPLICATION DIRECTIONS:

When geese have been determined to be a nuisance, Flight Control[®] Plus should be applied according to the following rates to the grassy, turf, or forage areas where geese are expected to feed/roost. To determine if the geese are a nuisance, a visual inspection (bird count) should be conducted by responsible officials / parties before application.

Grassy or Turf Areas, Landfills, Dumpsites:

- In most cases, dilute 2 quarts of Flight Control[®] Plus with 50 gallons of water and apply per acre of grass, turf or land surface (1.5 oz. Flight Control[®] Plus per 1,000 sq. feet). You might need to use as much as one gallon diluted in 50 gallons of water per acre for extreme bird pressure. Your supplier will provide individualized assistance on concentrations to be used under existing conditions.
- Mix with water based on spray equipment specifications and recommendations.
- Apply using a fine spray pattern to evenly distribute over entire surface to be treated.
- Allow material to dry before permitting human activity in the treated area.
- Spray at weekly intervals or as required by geese activity and anticipated seasonal migrations.
- When applying to turf, cutting of the lawn will reduce amount of repellent available.

US Consumer Product Safety Commission

STORAGE AND DISPOSAL

STORAGE:

Do not allow containers to freeze. After prolonged storage, product may separate. If this occurs, resuspend with agitation.

PROHIBITIONS

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticide or rinse is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Arkion Life Sciences also can be contacted for guidance on the disposal of pesticide wastes.

CONTAINER DISPOSAL (PLASTIC)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incinerator or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

CONDITIONS OF SALE AND WARRANTY:

Arkion Life Sciences warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. Since timing, method of application, weather and ground conditions, mixture with other chemicals, and other factors affecting the use of this product are beyond our control, no warranty is given concerning the use of this product contrary to label directions, or under conditions which are abnormal or not reasonably foreseeable.

Arkion MAKES NO OTHER WARRANTIES EITHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.

Handling, storage and use of the product by Buyer or User are beyond the control of Arkion and Seller. Risks such as ineffectiveness or other directions will be assumed by the Buyer or User.

IN NO CASE WILL ARKION OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT, NOR BE HELD RESPONSIBLE FOR INJURY OR LOSS AS A RESULT OF THE HANDLING OR USE OF THIS PRODUCT.

MANUFACTURED BY:



Wilmington, DE 19810

FLIGHT CONTROL[®] PLUS

FOR GEESE REPELLENCY

IMPORTANT!

Open and Read Label Before Use.

Contains Precautionary Statements, First Aid & Treatments and Directions For Use.
Replace Label In Pouch And Re-Seal After Reading.

MANUFACTURED BY:

ARKION LIFE SCIENCES

Wilmington, DE 19810

Avipel™

EPA Reg. No. 69969-79601-1

EPA Est. No. 62171-MS

ACTIVE INGREDIENT

9, 10 anthraquinone _____ 50%

OTHER INGREDIENTS _____ 50%

Total 100%

**For Best Results: Product may separate if allowed to sit.
Resuspend with agitation. Keep from freezing.**

KEEP OUT OF REACH OF CHILDREN CAUTION FIRST AID

- If inhaled:
- Move person to fresh air.
 - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
 - Call a Poison Control Center or Doctor for further treatment advice.
- If on skin or clothing:
- Take off contaminated clothing.
 - Rinse skin immediately with plenty of water for 15-20 minutes.
 - Call a Poison Control Center or Doctor for treatment advice.
- If in eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 - Call a Poison Control Center or Doctor for treatment advice.
- If swallowed:
- Call Poison Control Center or Doctor immediately for treatment advice.
 - Have person sip a glass of water if able to swallow.
 - Do not induce vomiting unless told to do so by the poison control center or doctor.
 - Do not give anything by mouth to an unconscious person.

FOR MEDICAL EMERGENCIES INVOLVING THIS PRODUCT, CALL TOLL FREE 1-800-424-9300.
HAVE THE PRODUCT CONTAINER OR LABEL AVAILABLE WHEN SEEKING TREATMENT ADVICE.

See side panel for additional precautionary statements.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing vapor or spray mist. Remove contaminated clothing and wash clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing.

PERSONAL PROTECTIVE EQUIPMENT:

When handling Avipel™ use long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment or disposal of waste. Apply this product only as specified on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

This product may be used to repel geese, including Canada geese.

For Professional Application on Structural Surfaces.

- Repels geese from terrestrial areas at or near airports.
- Repels geese from commercial sites, industrial sites, municipal sites or in developed urban areas.
- Repels geese from ornamental nurseries, and conifer nurseries.
- Repels geese from landfills and dumpsites.
- Repels geese from building roofs, window sills and ledges.

To prevent contamination of the dilute solution of Avipel™ by other chemical residues, be sure that the equipment is thoroughly clean before use or use dedicated equipment.

Apply this product using properly calibrated and maintained spray equipment. Do not apply when surface to be treated is wet or when rain is expected. **For best results, allow product to dry on surface prior to rainfall.**

For application by professional applicators only. Do not apply this product in a way that will contact workers or other persons, either directly or through drift.

MIXING DIRECTIONS:

Thoroughly shake or stir Avipel™ prior to diluting with water.

APPLICATION DIRECTIONS:

When geese have been begun to flock in one area and are problematic, apply Avipel™ according to the following rates to the areas where geese are expected to feed/roost. To determine if the geese are problematic, conduct a visual inspection (bird count) by a responsible officials/parties before application.

Landfills, Dumpsites:

- In most cases, dilute 2 quarts of Avipel™ with 50 gallons of water and apply per acre of surface (1.5 oz. Avipel™ per 1,000 sq. feet). You might need to use as much as one gallon diluted in 50 gallons of water per acre for extreme bird pressure. Your supplier will provide individualized assistance on concentrations to be used under existing conditions.
- Mix with water based on spray equipment specifications and recommendations.
- Apply using a fine spray pattern to evenly distribute over entire surface to be treated.
- Allow material to dry before permitting human activity in the treated area.
- Spray at weekly intervals or as required by geese activity and anticipated seasonal migrations.

Public, Municipal or Industrial Buildings:**Spray Application:**

- Apply at the rate of 3 fluid ounces (0.12 lb. a.i.) of Avipel™ diluted, in as much as 5 gallons of water per 1,000 square feet of building surface (roof, window sills, ledges) area.
- Mix with water based on spray equipment specifications and recommendations.
- Apply using a fine spray pattern to evenly distribute over the entire surface to be treated.
- Allow material to dry before permitting human activity in the treated area.
- Spray at weekly intervals or as required by geese activity and anticipated seasonal migrations.

Direct Surface Application:

- For use on solid surfaces, weekly intervals of repeated applications to the target surface are required when geese activity and anticipated seasonal migrations increase.
- Apply Avipel™ directly to the target surface using a paint brush, roller or similar direct application device at the rate of 3 fluid ounces (0.12 lb a.i.) per 1,000 sq. ft. of building surface.
- Avipel™ can be applied as is, without any additional dilution, at the rate specified above. Water can be added as required to dilute the product for direct surface application at the rate of 3 fluid ounces (0.12 lb. a.i.) per 1,000 sq. ft. of building surface.
- Allow material to dry before permitting human activity in the treated area.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

Pesticide Storage:

- Do not allow containers to freeze. After prolonged storage, product may separate. If this occurs, resuspend with agitation.

Pesticide Disposal:

Pesticide wastes are toxic. Improper disposal of excess pesticide or rinse is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Airepel LLC also can be contacted for guidance on the disposal of pesticide wastes.

Container disposal:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incinerator or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

CONDITIONS OF SALE AND WARRANTY:

Airepel LLC, warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. Since timing, method of application, weather and ground conditions, mixture with other chemicals, and other factors affecting the use of this product are beyond our control, no warranty is given concerning the use of this product contrary to label directions, or under conditions which are abnormal or not reasonably foreseeable.

AIREPEL, LLC MAKES NO OTHER WARRANTIES EITHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.

Handling, storage and use of the product by Buyer or User are beyond the control of Airepel LLC and Seller. Risks such as ineffectiveness or other directions will be assumed by the buyer or user.

IN NO CASE WILL AIREPEL LLC OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT, NOR HELD RESPONSIBLE FOR INJURY OR LOSS AS A RESULT OF THE HANDLING OR USE OF THIS PRODUCT.

DISTRIBUTED BY:

Airepel LLC

3521 Silverside Road, Wilmington, DE 19810

Avipel™

IMPORTANT!

Open and Read Label Before Use.

CAUTION - KEEP OUT OF REACH OF CHILDREN

Contains Precautionary Statements, First Aid, Treatments and Directions For Use
Replace Label In Pouch And Re-Seal After Reading.

DISTRIBUTED BY:

Airepel LLC

Wilmington, DE 19810

EPA Pesticide Reg. No. 02171-1-001

anthraquinone NYS DEC Letter - Application to Register 5/03

New York State Department of Environmental Conservation

Division of Solid and Hazardous Materials

Bureau of Pesticides Management, 9th Floor

625 Broadway, Albany, New York 12233-7254

Phone: (518) 402-8788 FAX: (518) 402-9024

Website: www.dec.state.ny.us

May 19, 2003

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Dr. Orn Adalsteinsson
Vice President
Arkion Life Sciences
Concord Plaza - Quillen Building
3521 Silverside Road
Wilmington, Delaware 19810

Dear Dr. Adalsteinsson:

Re: Application to Register the New Active Ingredient 9,10-Anthraquinone Contained in the Pesticide Product Flight ControlÆ Plus (EPA Reg. No. 69969-1)

The New York State Department of Environmental Conservation (Department) has completed review of the application (received 11/21/01) and supplemental information supplied to date regarding registration of the referenced product in New York State. Flight ControlÆ Plus (EPA Reg. No. 69969-1) contains the new active ingredient 9, 10-anthraquinone.

The Department's concerns regarding the potential risks to applicators and the public have been mitigated with the submission of revised Flight ControlÆ Plus product labeling received on May 12, 2003. This labeling bears a PERSONAL PROTECTIVE EQUIPMENT statement under the PRECAUTIONARY STATEMENTS section of the labeling and State of New York specific labeling text under the DIRECTIONS FOR USE section of the labeling:

FOR THE STATE OF NEW YORK USE THE FOLLOWING DIRECTIONS:

For Professional Application to Repel Geese at the Following Sites Only:

- Terrestrial areas at or near airports.
- Grassy areas at commercial sites and industrial sites.
- Golf courses, landfills and dumpsites.

With the incorporation of the above-specified text, use of the subject product, as labeled, should not pose

unreasonable risks to humans or to the environmental resources of New York State. Flight ControlÆ Plus can be useful as part of an integrated management program for reducing geese infestations, especially at airports. The Department accepts Flight ControlÆ Plus (EPA Reg. No. 69969-1) for registration as "Restricted Use" product in New York State. A synopsis of the review follows.

BACKGROUND:

The Flight ControlÆ (50% 9, 10-anthraquinone) product, as initially submitted, was labeled to repel geese, including Canada geese, from terrestrial areas at or near airports; from grassy areas at commercial sites, industrial sites, municipal sites, or in developed urban areas; from golf courses; and from landfills and dumpsites. Labeled application rate on/at grassy or turf areas, landfills, dumpsites is 2 quarts/acre (2.44 lb ai/acre) weekly or as required by geese activity and anticipated seasonal migrations. The maximum labeled application rate is to 4 quarts/acre (4.89 lb ai/acre). Product bears the text "For application by professional applicators only."

On January 14, 2002, the consultant for Arkion Life Sciences (Arkion) notified the United States Environmental Protection Agency (USEPA) regarding an alternate brand name (Flight ControlÆ Plus) for Flight ControlÆ. Arkion's petition to the Department to consider Flight ControlÆ Plus as a replacement product for Flight ControlÆ was accepted on November 12, 2002.

The registration package was deemed complete for purposes of technical review on June 24, 2002 following two determinations of incompleteness (01/08/02 and 03/15/02). Pursuant to the review timeframe specified in Environmental Conservation Law (ECL) §33-0704.2, a registration decision date of November 21, 2002 was established. By mutual consent, the registration decision date was waived so that the registrant could pursue revisions to the federal label which would address the New York State Department of Health's (NYSDOH) concerns regarding: (1) adequate protection for applicators; (2) use of the product in areas that pose significant exposure potential for the general public (e.g., schools, athletic fields, municipal sites and developed urban areas).

Toxicological risk assessments for 9, 10-anthraquinone and the Flight ControlÆ Plus product were conducted for the current application. Ecological effects and environmental fate reviews were not conducted since previous risk assessments anticipated no adverse effects to fish or wildlife and no impact to ground or surface water from the use of the product as labeled. Analytical methodologies for measuring 9,10-anthraquinone and its major degradates in soil and water were reviewed and deemed acceptable on September 13, 2002.

TOXICOLOGICAL RISK ASSESSMENT:

The Department's previous review (reference correspondence from S. Hammond to C. Koopman/Registration Consultant for Environmental Biocontrol International, dated January 27, 2000) of the subject product focused on a series of toxicological studies conducted by the National Toxicology Program (NTP) and the draft technical report "TR-494, Toxicological and Carcinogenesis Studies of Anthraquinone (CAS No 84-65-1) in F344/N Rats and B6C3F1 Mice (Feed Studies)." Flight ControlÆ is labeled for use in places where the public may contact treated surfaces (e.g., golf courses, municipal sites and developed urban areas). Product can also be applied repeatedly at rather high rates (up to 2.35 kilograms 9,10-anthraquinone per acre). Given the potential for exposure of workers and the general public to 9,10-anthraquinone from labeled use of Flight ControlÆ, and the fact that the draft NTP report has determined that this compound is carcinogenic, the NYSDOH expressed concerns in their previous registration reviews of the Flight ControlÆ product.

With the current submission, the registrant contends that the NTP cancer bioassay does not provide accurate information as to the potential carcinogenicity of 9,10-anthraquinone by submitting a recently published study (Butterworth et al. 2001). The preparation of anthraquinone used in the NTP cancer bioassay was contaminated with the mutagen 9-nitroanthracene (Mutagenesis 16: 169-177). A major finding reported, as indicated by the study's title, was that the 9,10-anthraquinone used in the NTP cancer bioassay was contaminated with 0.12 percent 9-nitroanthracene. 9-Nitro-anthracene has been shown to be genotoxic to bacterial cells (as evaluated in the Ames test) as well as to mammalian cells (as evaluated in the mouse lymphoma mutagenicity assay). The registrant believes that

positive findings from this latter assay greatly strengthens their argument that the 9-nitroanthracene contaminant could well have been responsible for all of the induced tumors in this NTP study. The NTP is aware of the contamination issue and have not released their final report pending further evaluation.

Although the registrant contends that the presence of 9-nitroanthracene used in the NTP cancer bioassays was responsible for the carcinogenic effects, the evidence for this is only indirect. Firstly, there are no data available on the carcinogenicity of 9-nitroanthracene to compare to the results from the NTP studies. Secondly, the registrant maintains that because the genotoxicity test results for 9-nitroanthracene were positive, it follows that this chemical possesses carcinogenic properties. While these positive results contribute to the weight of evidence for the carcinogenic potential of 9-nitroanthracene, this is still only suggestive evidence; a correlation exists between the results of genotoxicity assays and rodent carcinogenicity for some chemicals, but not for all chemicals. It is also not known whether the relatively low levels of 9-nitroanthracene measured in the NTP material, if this compound is carcinogenic, would be potent enough to cause the tumors reported.

Even if the NTP reversed their conclusion about the carcinogenic potential of that particular 9,10-anthraquinone material, the NYSDOH cannot assume that the registrant's 9,10-anthraquinone has no carcinogenic potential unless comparable cancer bioassays are performed. Moreover, the stated purity of the material used in the NTP study was about 99 percent 9,10-anthraquinone. The technical grade active ingredient material used to produce the Flight ControlÆ product is only 97.1 percent 9,10-anthraquinone. Arkion has indicated that one of these contaminants is 9-fluorenone at a level of less than 0.1 percent, but no information was given about the chemical composition of the remaining impurities that apparently comprise 2.8 percent of the technical material.

In an effort to address the concerns for risks to workers and the general public, the registrant submitted the results of an exposure study that they sponsored. In this study, Flight ControlÆ was applied to grass surfaces at the pesticide product label's directed application rate of approximately 0.066 milligrams per square centimeter (mg/cm²). Dislodgeable residues of 9,10-anthraquinone were measured by analyzing filter paper wipe samples taken on treated turf at one, two and twenty-four hours after application. The highest level detected in these samples was 0.000153 mg/cm² at one hour after treatment. The lowest level measured was 0.000039 mg/cm² at 24 hours after application. The analysis assumed that all of the dislodgeable material was available for dermal contact by the hands and forearms of an adult and there was 100 percent dermal absorption. It apparently only assumed one contact with the treated surface, not repeated contact as would be expected in most situations where the public visited a municipal site, golf course, etc. On this basis, the dose received by an adult weighing 70 kg was estimated to be 0.00568 mg/kg/day. Using a NOEL of 135 mg/kg/day from the 14-week rat study, the registrant calculated a margin of exposure (MOE) of about 24,000. This MOE is above the level of 100-fold normally considered by the USEPA to be adequate to protect the general public from non-cancer effects. However, this exposure scenario is not very conservative and one could assume that a child wearing typical summer clothing (e.g., shorts and a t-shirt) playing on treated turf at a municipal site would have considerably greater exposure.

The registrant did not submit any data on the exposure of workers involved in the application of Flight ControlÆ. To address this data gap, the NYSDOH used information in the Pesticide Handler Exposure Database to evaluate worker exposure and risk. It was assumed that workers were involved in both mixing and loading, and applied the product at the rate of 2.35 kg active ingredient/acre to a 10 acre area at weekly intervals for a period of 14 weeks. It also was assumed that dermal absorption was 100 percent. As per the label, it was assumed that no personal protective equipment was worn by the workers. Over the course of the 14-week period, the workers would be exposed to an average daily dose of about 11.5 mg/kg. This exposure level results in an MOE of only about 12-fold when compared to the NOEL of 135 mg/kg/day from the 14-week rat study. This MOE is less than the 100-fold level generally considered acceptable by the USEPA for worker risks.

The NYSDOH also estimated cancer risks to workers who apply Flight ControlÆ. No cancer potency slope factor was available for 9,10-anthraquinone, so a factor (0.043 mg/kg/day⁻¹) was calculated based on the liver tumor data for male mice as presented in the NTP carcinogenicity study. Using the same assumptions as presented above and also

assuming that workers apply Flight ControlÆ for 35 out of a 70 year lifespan, a lifetime average daily exposure of 1.54 mg/kg can be calculated. Using this exposure estimate and the cancer potency slope factor of 0.043 mg/kg/day-1, an increased lifetime cancer risk of 6.6×10^{-2} can be calculated. This risk level exceeds the 1×10^{-4} level generally considered by the USEPA to be acceptable for workers. The NYSDOH recognizes that the slope at higher exposures may differ from that at lower exposures, and the USEPA often considers exposures associated with a risk greater than or equal to 1 in 100 as being above the range where the slope factor can be applied. Nevertheless, estimated risks at this level indicate a risk level of concern.

There are no chemical specific federal or State drinking water/groundwater standards for 9,10-anthraquinone. Based on its chemical structure, 9,10-anthraquinone falls under the 50 microgram per liter general New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems). Using the cancer potency slope factor derived from the NTP data (0.043 mg/kg/day-1) and 6 NYCRR Part 702.4 procedures for deriving ambient water quality standards and guidelines based on oncogenic effects, the ambient water quality value associated with a one in a million increased lifetime cancer risk is 0.8 micrograms per liter for 9,10-anthraquinone.

The NYSDOH continued to have concerns regarding the risks posed to the general public and workers by Flight ControlÆ use, particularly if it were to be used at sites that have considerable exposure potential such as municipal sites and developed urban areas. Although the registrant submitted some relevant information to consider, the issue of whether 9,10-anthraquinone is carcinogenic has not been fully resolved, and until such time as it is, the NYSDOH must assume that this active ingredient poses cancer risks. Using the data available, the estimated cancer and non-cancer risks to workers are quite high, largely due to the lack of personal protective equipment required by the label. While the non-cancer risks estimated by the registrant for the general public were rather low, the exposure scenario employed is not conservative and does not account for children's exposure. Finally, the NYSDOH generally does not support registration of pesticide products if the ingredient(s) have carcinogenic potential, particularly when they are intended for application at high rates to areas that may be frequented by the general public, unless the needs are great.

On October 28, 2002, representatives of Arkion met with staff of the Department and the NYSDOH regarding the issues identified in the technical review (reference correspondence from S. Jackling to O. Adalsteinsson/ Arkion Life Sciences, dated October 2, 2002). At this meeting, the registrant presented data from a study they sponsored to evaluate the potential for exposure of the general public to 9,10-anthraquinone from Flight ControlÆ Plus use. In order for NYSDOH to evaluate the validity of this study and to revise their previous risk estimates, the registrant agreed to provide further information, including data on the use of Flight ControlÆ Plus by workers. The registrant also tentatively agreed to revise the Flight ControlÆ Plus label to include a requirement for workers to use personal protective equipment.

The NYSDOH reviewed the additional information provided by Arkion for the pesticide product Flight ControlÆ (now called Flight ControlÆ Plus). Some of the new information submitted by the registrant is a revision of an earlier study that evaluated the potential for dislodgeability of 9,10-anthraquinone residues from treated turf. In the revised study, Flight ControlÆ Plus was applied to grass surfaces within the range of the product label's directed application rate; in this case, 2.4 fluid ounces of Flight ControlÆ Plus per 1,000 square feet or approximately 0.042 milligrams of 9,10-anthraquinone per square centimeter (mg/cm²). The actual application rate of 9,10-anthraquinone, as measured by deposition cards, averaged 0.056 mg/cm². Dislodgeable residues of 9,10-anthraquinone were measured by analyzing filter paper wipe samples taken on treated turf at one, three and sixty-seven hours after application. The highest level detected in these samples represents residues of 0.000055 mg/cm² (0.1% of the actual average deposition rate) at one hour after treatment. The average level measured at 67 hours after application was 0.0000033 mg/cm² (0.01% of the actual average deposition rate). Using the highest dislodgeable residue level in conjunction with assumptions presented by the registrant at the October 28, 2002 meeting, the highest estimated doses of 9,10-anthraquinone for an adult and a child would be 0.002 milligrams per kilogram body weight per day (mg/kg/day) and 0.029 mg/kg/day, respectively. In estimating these doses, it was assumed that all of the dislodgeable material was available for dermal contact by the hands and forearms of an adult weighing 70 kg and by the near total body surface area of a child weighing 10 kg. It was further assumed that exposures occurred daily and that there was 100 percent dermal absorption. Using a no-observed-

effect level (NOEL) of 135 mg/kg/day from an NTP 14-week feeding study in rats, margins of exposure (MOEs) of about 67,500 and 4,700 can be calculated for adults and children, respectively. These MOEs are above the level of 100-fold or greater normally considered by the USEPA as adequate to protect the general public from non-cancer effects.

The registrant submitted some limited data on the exposure of workers involved in the application of Flight ControlÆ Plus. The worker exposure assessment previously conducted by the NYSDOH using information in the Pesticide Handler Exposure Database estimated an average daily dose of about 11.5 mg 9,10-anthraquinone/kg for a 14-week period of use. Based on actual use data, the registrant estimated worker exposure to be about 0.7 mg/kg/day for this time period. In both the registrant's and NYSDOH's exposure assessment it was assumed that workers were not wearing any personal protective equipment as per the label. From these average daily dose estimates of 11.5 mg/kg (NYSDOH derived value) and 0.7 mg/kg (registrant's derived value), respective MOEs of about 12 and 190 can be calculated when compared to the NOEL of 135 mg/kg/day from the 14-week rat study. While the NYSDOH-derived MOE is less than that which is generally considered acceptable by the USEPA, the use of personal protective equipment by workers (long-sleeved shirt and long pants, socks and shoes, protective eyewear, chemical-resistant gloves) would considerably reduce the average daily dose estimate and increase the MOE. Based on the use data supplied by the registrant and information in the Pesticide Handler Exposure Database, exposure estimates for the 14-week period considered would be about 0.0012 mg/kg/day if personal protective equipment were worn. This revised non-cancer exposure estimate results in an MOE of about 112,500.

The registrant also submitted a detailed report of a 90-day rat dietary toxicity study with 9,10-anthraquinone. In this study, hematological effects and histopathology of the liver and kidney occurred at the lowest dose level (16 mg/kg/day). Thus, a NOEL was not identified. The reported effects from this study are consistent with those of the subchronic rat study in the NTP draft report, but occurred at a lower dose level. The lowest-observed-effect level (LOEL) from this study (16 mg/kg/day) can be used instead of the NOEL from the NTP study (135 mg/kg/day) to calculate MOEs. An MOE so derived would be about 13,000 for workers wearing personal protective equipment and applying Flight ControlÆ Plus as per the registrant's data. Because this MOE was derived using a LOEL instead of a NOEL, an MOE of 1,000-fold or greater would be considered adequate. The revised MOEs for adults and children from contacting surface residues would be about 8,000 and 550, respectively. Thus, the MOE for children may not be adequately protective.

In the previous NYSDOH review of Flight ControlÆ Plus, an increased lifetime cancer risk level of 6.6×10^{-2} for workers was calculated. This cancer risk level exceeds the 1×10^{-4} level generally considered by the USEPA to be acceptable for workers. However, assuming that workers wear personal protective equipment and apply Flight ControlÆ Plus as the registrant's use data indicated, NYSDOH recalculated an increased lifetime cancer risk level for workers to be 2.6×10^{-5} . This estimate is based on a calculated lifetime average daily exposure of 6.0×10^{-4} mg/kg/day and a cancer potency slope factor of 0.043 mg/kg/day⁻¹.

Arkion's proposal to add personal protective equipment requirements ("long-sleeved shirt and long pants, sock and shoes, protective eyewear and rubber gloves") to the Flight ControlÆ Plus label was considered. Based on the new use data submitted, and a requirement for workers to wear personal protective equipment, a reassessment indicates that risks to workers would be within the range that the USEPA considers acceptable. However, given the carcinogenic potential of 9,10-anthraquinone, the NYSDOH continued to have concerns for the use of Flight ControlÆ Plus, particularly in settings that have significant exposure potential for the public (e.g., schools, athletic fields, municipal sites and developed urban areas). With respect to the registration of Flight ControlÆ Plus use at sites where public contact will be negligible (e.g., at airports, landfills, dumpsites and commercial/industrial sites), the NYSDOH did not object if the Department determined that there is a need and that these uses would not pose other concerns.

The NYSDOH initially had concerns for use of Flight ControlÆ Plus at golf courses. However, upon further evaluation, NYSDOH does not object to the use of this product at these sites. The registrant has indicated that treatments will be confined to limited areas in golf courses (this is reportedly the case with other sites as well) due to the habits of resident geese populations and the specifics of the product. Also, given the minimal dislodgeability of the

9,10-anthraquinone residues on grass, and the limited likelihood that golfers will have direct dermal contact with sizeable areas of treated turf, exposure and risks to golfers should be negligible.

MITIGATION:

In order to mitigate the NYSDOH's concern for potential risks to workers and the general public, the registrant pursued revisions to the federal label. The USEPA stamped label, dated May 7, 2003, bears the PERSONAL PROTECTIVE EQUIPMENT statement "When handling Flight ControlÆ Plus use long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves" under the PRECAUTIONARY STATEMENTS section of the labeling. Arkion submitted a notification to USEPA, dated May 8, 2003, regarding the addition of State of New York specific labeling text which contains a reduced list of use sites as compared to the federally approved label. The Flight ControlÆ Plus product labeling received on May 12, 2003 bears the following text under the DIRECTIONS FOR USE section of the labeling:

FOR THE STATE OF NEW YORK USE THE FOLLOWING DIRECTIONS:

For Professional Application to Repel Geese at the Following Sites Only:

- Terrestrial areas at or near airports.
- Grassy areas at commercial sites and industrial sites.
- Golf courses, landfills and dumpsites.

When used as labeled, the Flight ControlÆ Plus product bearing updated labeling should not cause unreasonable adverse effects to humans or the environment. The Department hereby accepts Flight ControlÆ Plus (EPA Reg. No. 69969-1) for registration as a "Restricted Use" pesticide product in New York State. Enclosed for your files are the Certificate of Pesticide Registration and New York State stamped-"ACCEPTED" labeling.

Flight ControlÆ Plus, as noted in the "RESTRICTION" column on the Certificate, is classified as "Restricted Use" under rules and regulations 6 NYCRR 326.2(g). As such, this product is restricted in its purchase, distribution, sale, use and possession in New York State.

According to Department regulations specified in 6 NYCRR 326.3(a): "It shall be unlawful for any person to distribute, sell, offer for sale, purchase for the purpose of resale, or possess for the purpose of resale, any restricted pesticide unless said person shall have applied for, and been issued a commercial permit." If you require information regarding a commercial permit, please contact Thomas Lynch, Chief, Pesticide Certification Section, at (518) 402-8748.

The Pesticide Reporting Law (PRL) requires all certified commercial pesticide applicators to report information annually to the Department regarding each pesticide application they make. Commercial pesticide retailers are required to report all sales of restricted pesticide products and sales of general use pesticide products to private applicators for use in agricultural crop production. If no sales are made within New York State, a report still must be filed with the Department indicating this is the case. Information relating to the Pesticide Reporting Law or annual report forms is available at the Department's website at <http://www.dec.state.ny.us> or at 1-888-457-0110 (toll free within New York State). Out-of-State callers may contact the Pesticide Reporting Section at (518) 402-8765.

Please note that a proposal by Arkion Life Sciences, or any other registrant, to register a product containing 9,10-anthraquinone, whose labeled uses are likely to increase the potential for significant exposure to humans or impact to the environment, would constitute a major change in labeled (MCL) use pattern. Such an application must be accompanied by a new application fee and meet the requirements specified in 6 NYCRR Part 326.17.

Please contact Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768 if you have any questions.

Sincerely,

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosures

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For more information relative to pesticides and their use, please contact the PMEP staff at:

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Questions regarding the information and development within this web site should be directed to the [PMEP Webmaster](#).

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